

### **Request for Continued Examination**

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed 05/28/10 has been entered.

### **Applicants' Amendments**

2) Acknowledgment is made of Applicants' amendments filed 05/28/10 and 11/30/2010 in response to the advisory action mailed 04/07/10.

### **Examiner's Amendment**

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by attorney Otis Littlefield during a telephonic interview on 04 April 2011.

The instant application has been amended as indicated below.

(a) The limitation 'Tween' at line 21 of page 4 of the specification is replaced with the limitation --TWEEN--.

(b) The limitation 'Span' at line 21 of page 4 of the specification is replaced with the limitation --SPAN--.

(c) Claim 29 has been canceled.

(d) New claim 31 has been added as set forth below.

--Claim 31 (New). A method of inducing an immune response in a subject comprising administering an immunologically effective amount of the immunogenic composition of any one of claims 17, 20-22 and 24-28.--

### **Status of Claims**

- 4) Claim 17 has been amended via the amendment filed 11/30/10.  
Claims 18 and 19 have been canceled via the amendment filed 11/30/10.  
Claim 29 has been canceled via this Examiner's amendment.  
New claim 31 has been added via this Examiner's amendment.  
Claims 17, 20-22, 24-28, 30 and 31 are pending and are under examination.

### **Information Disclosure Statement**

- 5) Acknowledgment is made of Applicants' Information Disclosure Statement filed 11/08/10. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Rejection(s) Moot**

- 6) The rejection of claims 18 and 19 made in paragraph 12 of the Office Action mailed 04/20/09 and maintained in paragraph 8 of the Office Action mailed 12/28/09 and paragraph 7 of the Advisory Action mailed 04/07/10 under 35 U.S.C § 103(a) as being unpatentable over Granoff et al. (Infect. Immun. 65: 1710-1715, May 1997, of record) (Granoff et al., 1997) in view of Granoff et al. (J. Pediatr. 121: 187-194, 1992, of record), Vella et al. (Biotechnology 20: 1-22, 1992, of record) and Frasc (In: Development and Clinical Uses of Haemophilus B conjugate Vaccines. (Ed) Willis et al. M. Dekker, New York, pages 435-453, 1994, of record), is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Withdrawn**

**7)** The rejection of claim 28 made in paragraph 14 of the Office Action mailed 12/28/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

**8)** The rejection of claims 17, 22 and 25 made in paragraph 12 of the Office Action mailed 04/20/09 and maintained in paragraph 8 of the Office Action mailed 12/28/09 and paragraph 7 of the Advisory Action mailed 04/07/10 under 35 U.S.C § 103(a) as being unpatentable over Granoff et al. (Infect. Immun. 65: 1710-1715, May 1997, of record) (Granoff et al., 1997) in view of Granoff et al. (J. Pediatr. 121: 187-194, 1992, of record), Vella et al. (Biotechnology 20: 1-22, 1992, of record) and Frasch (In: Development and Clinical Uses of Haemophilus B conjugate Vaccines. (Ed) Willis et al. M. Dekker, New York, pages 435-453, 1994, of record), is withdrawn in light of Applicant's amendment to the base claim and Applicant's arguments with regard to the unpredictability issue associated with the use of MF59 with OMV at the time of the invention.

**9)** The rejection of claim 21 made in paragraph 13 of the Office Action mailed 04/20/09 and maintained in paragraph 9 of the Office Action mailed 12/28/09 and paragraph 8 of the Advisory Action mailed 04/07/10 under 35 U.S.C § 103(a) as being unpatentable over Granoff et al. (Infect. Immun. 65: 1710-1715, May 1997, of record) (Granoff et al., 1997) as modified by Granoff et al. (J. Pediatr. 121: 187-194, 1992), Vella et al. (Biotechnology 20: 1-22, 1992) and Frasch (In: Development and Clinical Uses of Haemophilus B conjugate Vaccines. (Ed) Willis et al. M. Dekker, New York, pages 435-453, 1994) as applied to claim 17, and further in view of Dalseg et al. (In: Vaccines 96. (Ed) Brown F. Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., pages 177-182, 1996, of

record), is withdrawn in light of Applicant's amendment to the base claim and Applicant's arguments.

**10)** The rejection of claim 24 made in paragraph 14 of the Office Action mailed 04/20/09 and maintained in paragraph 9 of the Advisory Action mailed 04/07/10 under 35 U.S.C § 103(a) as being unpatentable over Granoff et al. (Infect. Immun. 65: 1710-1715, May 1997, of record) (Granoff et al., 1997) as modified by Granoff et al. (J. Pediatr. 121: 187-194, 1992, of record), Vella et al. (Biotechnology 20: 1-22, 1992) and Frasci (In: Development and Clinical Uses of Haemophilus B conjugate Vaccines. (Ed) Willis et al. M. Dekker, New York, pages 435-453, 1994) as applied to claim 17, and further in view of Seid (US 6,638,513, of record) ('513) or Granoff (WO 98/58670) ('670), is withdrawn in light of Applicant's amendment to the base claim and Applicant's arguments.

### **Relevant Art**

**11)** The art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure.

In July of 2004, Fukasawa et al. (FEMS Immunol. Med. Microbiol. 41: 205-210, 01 July, 2004) provided evidence for inclusion of MF59 to enhance the immune response against meningococcal OMV. See abstract. Fukasawa et al. concluded that the use of MF59 as adjuvant might improve the immunogenicity induced by OMV vaccines against serogroup B N. meningitidis in infants. Fukasawa et al. stated that it would be possible to propose a serogroup B/C vaccine using only OMV strain N44/89 conjugated to serogroup C meningococcal capsular polysaccharide and MF59 as adjuvant and expect that this vaccine will promote efficient induction of high avidity and bactericidal antibodies. See page 209.

## Remarks

**12)** Claims 17, 20-22, 24-28, 30 and 31, now renumbered as claims 1, 2-4, 5-9, 10 and 11 respectively, are allowed.

New claim 31 has support in canceled claim 29, second full paragraph on page 3, lines 10-13 of page 2; and the paragraph bridging pages 4 and 5 of the instant specification.

**13)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**14)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**15)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to

4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

/S. Devi/  
Primary Examiner  
AU 1645

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